

REMARKS

The claimed invention

Claim 1 recites a method for making cartilage. The method comprises exposing a suspension of dissociated cells that form cartilage in a solution of biocompatible polymer to free radicals generated by electromagnetic radiation from an electromagnetic source external to the suspension so that the electromagnetic radiation generates free radicals which cause polymer crosslinking and forms a semi-interpenetrating or an interpenetrating polymer network. Claims 12-23 have been added to the application. Applicant submits that these claims are supported by the specification for example, support for Claim 12 can be found in the specification at page 4, line 15-page 6 line 16; page 16, line 4-9; and page 19, line 28-page 20, line 28. Claims 13-19 are supported by material throughout the specification and by claims 1-7 as originally filed. Support for claim 20 may be found, for example, at page 17 line 16-page 18 line 2. Support for claims 21 and 22 may be found, for example, at page 19, line 27-page 20, line 4 and lines 9-28. Support for claim 23 may be found, for example, at page 19, lines 21-26. Referring to the Office Action dated July 12, 2002 (Paper No. 6), Applicant submits that new claims 12 and 20-23 are generic. Claim 13 and the claims dependent therefrom correspond to a method of making cartilage.

Applicant submitted a supplemental response to the official action mailed July 12, 2002 (Paper Number 6) on November 1, 2002. It appears that the amendment was not entered into the record and that the Examiner did not consider it before issuing the Office Action dated November 26, 2002. As a result, Applicant believes that claims 1-7 are still pending in the application and introduces claims 12-23 herewith. Claims 12-23 correspond to the claims that were submitted with the supplemental response dated November 1, 2002.

The cited art

Soon-Shiong discloses biocompatible materials, for example lipids, polycations, and polysaccharides that may be polymerized by exposure to particular wave lengths of radiation (Abstract). Cells may be added to the crosslinked materials (Example 25; column 4, lines 1-15).

Vacanti discloses the use of mesh-like structures of fibrous polymers for culturing chondrocytes to form cartilage (column 6, lines 47-50, Abstract).

Rejections under 35 U.S.C. § 112

Claims 1-7 stand rejected under 35 U.S.C. § 102, second paragraph, as being indefinite. The Examiner states that, in Claim 1, the term “cells” is vague. Applicant respectfully disagrees. Applicant submits that one skilled in the art would understand the metes and bounds of the claim. Nonetheless, in the interests of facilitating prosecution, Applicant has clarified the claims by amending claim 1 to recite that the dissociated cells are cells that form cartilage, as disclosed on page 16, line 5. This class of cells includes chondrocytes, which produce articular cartilage, and cells that produce other types of cartilage. Applicant submits that the amendment does not narrow the scope of the claim because the preamble of the claim recites the production of cartilage.

Claims 1-7 stand rejected under 35 U.S.C. § 112, first paragraph, for failure to meet the enablement requirement. Applicant respectfully disagrees. The examples described in the specification teach how to practice the invention with PEO, a mixed anhydride of succinic acid and poly(ethylene oxide) and dimethylacrylate (DMA). Example 4, in particular, describes an exemplary initiator and describes how to choose the dose of alternative initiators. The examples provide techniques that can be applied to other polymers that are formed through radical polymerization. Exemplary polymers are disclosed at page 6, lines 4-14 and page 11, lines 9-24. Additional polymers are well known to those skilled in the art and are described, for example, in PCT Publication WO96/40304, cited at page 5, line 23, and academic references such as the Concise Encyclopoedia of Polymer Science and Polymeric Amines and Ammonium Salts, cited at page 12, line 16-18. The references describe monomers that polymerize through radical chain mechanisms and describe standard initiators and reaction conditions. The specification, especially the examples, teach how to adjust these standard reaction conditions for use with the invention. Claim 1 has been amended to recite the formation of a semi-interpenetrating or an interpenetrating polymer network to clarify the relationship of the claims to the teachings of the disclosure. Applicant submits that claims 1-7 and 12-23 meet all the requirements of 35 U.S.C. § 112.

Rejections under 35 U.S.C. § 103

Claims 1-7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Soon-Shiong in view of Vacanti. Applicant respectfully disagrees. Soon-Shiong discloses a method in which a polymer is exposed to electromagnetic radiation, following which cells are added to the

crosslinked polymer. Vacanti fails to disclose crosslinking a polymer; rather, Vacanti discloses seeding cells onto a fibrous matrix. Neither Soon-Shiong nor Vacanti disclose or suggest combing cells with a polymer or polymer precursor *before* exposing the polymer to electromagnetic radiation. In contrast, Applicant submits that claim 1 recites a method in which a suspension of cells in a solution of a polymer is exposed to electromagnetic radiation. The combination of Soon-Shiong and Vacanti does not result in or suggest the claimed invention because neither reference teaches or suggests exposing a suspension of cells in a polymer solution to electromagnetic radiation, as recited in the pending claims. Applicant submits that claims 1-7 and new claims 12-23 are patentable in view of Soon-Shiong and Vacanti, whether considered separately or together.

Rejections for Double-Patenting

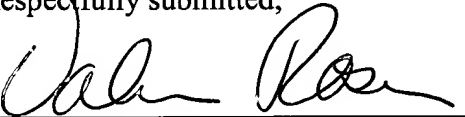
Claims 1-7 stand rejected under the doctrine of obviousness-type double-patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,224,893. Without agreeing with the propriety of this rejection, Applicant respectfully defers deciding whether to file a terminal disclaimer until all other rejections of the claims have been overcome.

Petition to Revive

Applicant unintentionally failed to respond to the Office Action dated November 26, 2002. Applicant respectfully submits a Petition to Revive herewith.

Please charge any fees associated with this filing, or apply any credits, to our Deposit Account No. 03-1721.

Respectfully submitted,



Valarie B. Rosen
Registration Number 45,698
Date: October 22, 2004

Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109
(617) 248-5000